

K964309

APR 22 1997

Attachment C

510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

1) Submitter's Name / Contact Person: Paul Schrader

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Date Summary was prepared: October 14, 1996

2) Trade Name: Sonos 2500 Ultrasound Imaging System

Common Name : Ultrasound Imaging System

Classification Pro Codes: 90 IYN & 90 IYQ

3) Identification of Predicate Device:

There are two predicate devices used for this submittal. One predicate device for this submittal is the existing SONOS 2500 system which was reviewed by FDA with K934041 and found to be SE on September 22, 1994. The second predicate device is the ATL HDI 3000 system which was reviewed by FDA with K935009 and found to be SE on October 11, 1994

4) Description of the device or modification being submitted for premarket approval.

Functionality: This modification allows for transmission of an ultrasound signal at one frequency and receipt of the returning echo at a different frequency.

Scientific Concepts: Rayleigh's theory predicts that a bubble resonating in an ultrasound field will radiate harmonic echoes at twice the frequency of the incident beam and that the harmonic echoes can be stronger than the fundamentals. Ultrasound contrast agents are made from many small bubbles. A minor system modification is made to be able to detect these harmonic echoes

Significant Characteristics of the Modification: New transducer, component modifications to two circuit boards and SW to recognize/drive the new transducer.

Significant Safety Concerns: None

FDA is reviewing the safety of contrast agents. Addition of harmonic imaging to the ultrasound systems does not increase ultrasound output relative to normal and fundamentals contrast imaging. The harmonic imaging modification only affects receive operation of the system.

5) Statement of Intended Use: No change from existing SONOS 2500 platform reviewed during 510(k) 934041

6) Predicate Device Comparison:

There are many ultrasound devices on the market that have the ability to image contrast agents and also have the ability to vary transmit and receive frequencies. This submittal uses two systems (HP Sonos 2500 and ATL HDI 3000) for predicate device comparisons.